

REMARKS

Claims 1-34 are currently pending in the application. Claims 1-2, and 23-34 are withdrawn. Claim 11 is amended. The amendments find support in the specification and are discussed in the relevant sections below. No new matter is added.

Claim Objections

The Examiner has objected to claims 11 and 13 under 37 C.F.R. 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or cannot depend from any other multiple dependent claim. Applicants submit that they have amended claim 11 to delete the reference to claim 2, and to instead, expressly recite the elements of claim 2. Amendment of claim 13 is not required, because, given the amendment of claim 11, multiple dependent claim 13 no longer depends from another multiple dependent claim.

Rejection of claims 3-5 and 10 under 35 U.S.C. §101

The Examiner has rejected claims 3-5 and 10 under 35 U.S.C. §101 as being directed to non-statutory subject matter. The Examiner contends that the DNA, as claimed, has the same characteristics and utility as that found in nature and therefore does not constitute patentable subject matter. Applicants respectfully disagree.

The rejected claims recite the polynucleotide sequences of SEQ ID NO: 3 and 4. As shown in Table 1 of the specification on page 13, SEQ ID Nos. 3 and 4 are each molecular beacon probes. The specification teaches that a molecular beacon is a single-stranded polynucleotide probe that possesses a stem-and-loop hairpin structure (page 9). A review of the sequence of SEQ ID NOS 3 and 4 relative to the binding target shown in Figure 1, shows that while the loop portion of the molecular beacon is complementary to a portion of the target sequence, the sequence forming the stem of the molecular beacon is not complementary to the target; that is, the molecular beacon is not the natural complement of a natural sequence. The specification also teaches that the molecular beacons “were custom synthesized and purified at Midland Certified Reagent Company (Midland, TX)”. Thus, the claimed polynucleotide

molecules are necessarily synthetic. The molecular beacon molecules embodied by SEQ ID Nos. 3 and 4 are synthetic, and custom designed to have the ability to bind to a target sequence, and form a stem loop structure.

The Examiner has aptly cited *Diamond v. Chakrabarty* to support the position that in the absence of the hand of man, a naturally occurring polynucleotide is considered non-statutory subject matter. In contrast to the Examiner's assertion of non-statutory subject matter, Applicants submit that the claimed polynucleotides only exist because of the "hand of man. Accordingly, Applicants submit that the claims meet the statutory requirement set out in 35 U.S.C. §101

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

Date: 3/19/09


Name: Kathleen M. Williams
Registration No.: 34,380
Customer No.: 27495
Palmer & Dodge LLP
111 Huntington Avenue
Boston, MA 02199-7613
Tel. (617) 239-0100